RUHR-UNIVERSITÄT BOCHUM

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OFFICIAL NOTICE

Directives of the Ethics Committee of the Faculty of Sports Science (ECS) Ruhr-University Bochum

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RUB

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28. October 2016

On the basis of §§ 2 sec. 4 and § 26 sec. 3 of the law on the universities of the state of North Rhine-Westphalia (HG) in the version of the University Act for the Future (Hochschulzukunftsgesetzes) of 16.09.2014 (GV. NRW. Page 547), last amended by the law of 14th June 2016 (GV. NRW. Page 310), and article 28 sec. 1 of the constitution of the Ruhr-University Bochum (VerfRUB) of 16.07.2015 (Official announcements of the Ruhr-University Bochum [AB] No 1063 of 21.08.2015), last amended by the order of 13.11.2015 (AB No 1122), the Ethics Committee of the Faculty of Sports Science issues the following directives:

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§ 1 General and basic principles

As per § 10 sec. 1 of the faculty regulations of the Faculty for Sports Science of the Ruhr-University Bochum of 30.10.2015 (AB No 1116) in the amended version of 30.08.2016 (AB No 1163), the permanent local Ethics Committee for Sports Science (ECS) shall become operative upon the order of the Faculty Council or the Dean.

The local ethics committee of the Faculty for Sports Science (ECS) of the Ruhr-University Bochum is an independent body that examines and assesses the ethical permissibility of sports science research projects before they are carried out, unless this is regulated through other mandatory provisions or the responsibility lies with the Medical Ethics Committee. Applications from the Faculty for Sports Science are subject to the assessment and/or applications involving at least one member of the faculty engaged in the research project. The ECS makes its assessment by drawing upon the ethical guidelines of the relevant expert associations as well as the ethical principles for sports science. The ECS acts by order of the faculty. The ECS, its members as well as scientists appointed to assist the assessment, carry out their tasks independently and are not bound to observe instructions. They are only responsible to their conscience. The accountability of the scientist responsible for leading the studies or the relevant scientist remains unaffected.

§ 2 Status and structure

- (1) The ECS comprises of at least three scientists from the group of university professors as well as at least two PhD representatives from the scientific non-professorial teaching staff whereby a majority of professors must be assured. The members of the ECS represent the various subject areas at the faculty taking into account any staffing factors.
- (2) The members of the ECS are appointed by the members of the Faculty Council for a period of three years.
- (3) A chairperson and deputy chairperson are appointed by the members of the ECS.
- (4) The names of the members of the ECS are published.
- (5) The Ethics Committee may, if necessary, appoint also other, external knowledgeable experts to make decisions.
- (6) ECS member applications are processed by independent members of the Ethics Commission.

§ 3 Tasks and responsibilities

- (1) The ethics commission examines and, if necessary, gives an opinion on the ethical aspects of planned human research projects. The commission's chairperson takes a stand with regards to the applications on behalf of the faculty. Advice on legal or ethical concerns is not given.
- (2) Cases, which require the professional (medical) competence of the ethics committee of RUB's medical faculty for their assessment, are either referred to the same or an external appraiser with the relevant experience is appointed in the course of the assessment. This is the case, when the research projects pursue medical questions in accordance with the Medicines Act or the Medicine Product Law. Possible costs incurred are borne by the teaching and research department responsible.
- (3) The Ethics Committee examines in particular, whether
 - 1. All precautions have been taken to minimise risks to the test persons
 - 2. The project has a reasonable balance of benefits and risks
 - 3. The test persons' consent or that of their legal representatives is sufficiently documented
 - 4. The project implementation complies with the relevant legal provisions, in particular data protection regulations.

§ 4 Types of procedure and implementation

- (1) The appraisal of the research project is carried out when the responsible scientist makes an application. Students' applications require a written confirmation by the relevant supervising scientist or the university lecturer in charge.
- (2) The processing of applications is subject to the condition that the research project had not previously been submitted to any other ethics committee for appraisal.

A relevant applicant statement must be attached to the documents. The ECS provides the appropriate documents/checklists/instructions to prepare the application documents. The application documents must be submitted to the ECS electronically. In addition, the original signed application (without attachments) must be available.

- (3) Applications can be submitted to the ECS, covering the following categories of sports science research:
 - 1. Category 1 Examinations, measurements, tests and surveys, which do not particularly stress the tested persons during the course of the research project or do not, physically or psychologically, affect them beyond an everyday level.
 - 2. Category 2 Examinations, measurements, tests and surveys, which particularly stress the tested persons during the course of research project or, physically or psychologically, affect them beyond an everyday level.
 - 3. Category 3 Examinations, measurements, tests and surveys of categories 1 or 2 in combination with vulnerable groups (in particular people with restricted health, children/young or elderly people) as well as research projects requiring external expertise or implying that the competence of the ethics commission of the RUB medical faculty is needed.
- (4) Applications to the Ethics Committee should have the following information regarding:
 - 1. Study director and title of the study
 - 2. Type, aim and plan of the research project
 - 3. Type and number of the test subjects as well as criteria for their selection e.g. the necessity to include vulnerable groups of test candidates, particularly people of restricted health, children, young or elderly people
 - 4. All steps in the research process
 - 5. Presentation of potential conflicts of interest
 - 6. Stresses and risks for test subjects including possible consequences and precautions, which avoid negative effects; this applies particularly against the background of vulnerability of the test subject group (e.g. particularly people of restricted health, children, young or elderly people)
 - 7. Arrangements for explaining the research process to the test candidates in written and if necessary verbal form and obtaining written consent to participate in the research. Printed forms to be used must be attached.
 - 8. Opportunities for the test candidates to reject or withdraw participation
 - 9. Protocols for guardians and carers giving consent for the participation of minors and test subjects with limited capabilities to make decisions (e.g. children, people unable to work)
 - 10. If necessary, insurance cover provided
 - 11. Data registration (especially for sound and video recordings and computer protocols) and data storage under the aspect of data encryption
 - 12. Study leader consent to report adverse events during or at the end of the study to the ethics committee

- (5) Application documents
 - 1. The application consists of a form issued by the ECS and completed by the applicant, which has a checklist and a list of processes currently applied in sports science as well as, if necessary, further relevant documentation stipulated by the ECS in the course of the application process.
 - 2. The ECS is responsible for further development of the application documents.

§ 5 Assessment and approval

- (1) The ECS prepares statements on the basis of at least two appraiser votes. The chairperson drafts a statement when there are two positive votes or conditional positive votes with provisions and refers the application with the notification to all members of the committee. In consultation with the committee, the chairperson may negotiate the applications orally on the basis of the votes and his/her opinion. An oral negotiation is obligatory when vulnerable test candidate groups are involved.
- (2) The ECS appoints the expert appraisers. The appraisers are post-doctorial scientists of the faculty of sports science. The committee allocates appraisers appropriate to the application.
- (3) Each appraiser submits his/her vote to the committee's chairperson. The ECS chairperson determines the appraisers through a circular procedure.
- (4) In consultation with the committee, the chairperson may ask one or several additional professional experts for their vote. Additional experts are provided with the entire application. The responsible teaching and research department bears the possible cost incurred.
- (5) Members participating in the research project or who have a conflict of interest, which may affect their bias, are excluded from the appraisal or the decision-making discussion.
- (6) Written decision-making in circular form is permitted. The chairperson can make the final decision on their own when both appraisers give positive votes and no committee member objects. Usually, an application should get a decision within four weeks.
- (7) The committee may request that the applicant gives an oral explanation of the research project or submits supplementary documentation, information or justifications.
- (8) If there are reservations in whole or in part against the application, then the applicant may be asked to submit a revised application.
- (9) The Ethics Committee may hear the applicant before a decision is made. He/she must be heard upon his/her request.
- (10) The decision of the Ethics Committee must be given to the applicant in writing. Rejections, provisions and recommendations to amend the research project must be justified in writing.
- (11) When an application is rejected on ethical grounds, then the applicant may submit counterarguments and request a new opinion from the committee one-time.

- (12) Decisions of the Ethics Committee require a simple majority of the members. When a decision is taken then this is in principle a decision of the Ethics Committee as a whole.
- (13) The chairperson may consider multicentre studies, which had already been assessed by other committees. The committee must be informed and can deal with it in cases of doubt.
- (14) Meetings of the Ethics Committee are not public. Its findings must be recorded in the minutes of the meetings. Meetings are held regularly.

§ 6 Confidentiality of the Ethics Review

- (1) The subject of the review and the statements of the Ethics Committee must be held in confidence. The members of the committee are bound to secrecy. The same applies to appointed experts. Individual votes are confidential.
- (2) The members of the Ethics Committee must be instructed of their obligation to maintain confidentiality at the beginning of their task.
- (3) Committee votes, application documents, minutes of meetings, amendments, interim and final reports, written communication etc. are archived electronically.
- (4) Data protection must be observed when archiving the application documents.

§7 Taking effect

This regulation comes into effect the day after publication in the official announcements of the Ruhr-University.

Drawn up on the basis of the resolution of the Faculty Council of the Faculty for Sports Science of 13.07.2016.

Bochum, on 28th October 2016

The Rector Ruhr-University Bochum University Professor Dr Axel Schölmerich